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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/376,911 08/18/99 MICHON

F 1758-4043US1

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HM22/0328

EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/376,911	Applicant(s) Michon et al.	
	Examiner S. Devi, Ph.D.	Group Art Unit 1645	[Barcode]

☒ Responsive to communication(s) filed on 01/11/01.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-58 ~~is~~ are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-58 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Electi n / Restriction

- 1) Claims 1-58 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 7 and 15, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *E. coli* K1, classified in class 424, subclass 257.1
 2. Claim 7, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *E. coli* K92, classified in class 424, subclass 257.1
 3. Claim 7, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of type 4 *Pneumococcus*, classified in class 424, subclass 244.1
 4. Claims 7 and 15, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of type 14 *Pneumococcus*, classified in class 424, subclass 244.1
 5. Claim 7, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of group A *Streptococcus*, classified in class 424, subclass 244.1
 6. Claim 7, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of group C *Streptococcus*, classified in class 424, subclass 244.1
 7. Claims 3, 17 and 38, drawn to a polysaccharide-protein conjugate comprising an

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- N-propionated polysaccharide of a yeast, classified in class 424, subclass 274.1
8. Claims 3, 17 and 38, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of a cancer cells, classified in class 424, subclass 277.1
 9. Claims 3 and 17, drawn to a polysaccharide-protein conjugate comprising an N-propionated chemically synthesized polysaccharide, classified in class 514, subclass 23.
 10. Claims 4 and 39, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *Haemophilus*, classified in class 424, subclass 256.1
 11. Claims 4 and 39, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *Neisseria*, classified in class 424, subclass 249.1
 12. Claims 4 and 39, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *Salmonella*, classified in class 424, subclass 258.1
 13. Claims 4 and 39, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *Klebsiella*, classified in class 424, subclass 259.1
 14. Claims 4 and 39, drawn to a polysaccharide-protein conjugate comprising an N-propionated polysaccharide of *Pseudomonas*, classified in class 424, subclass 260.1
 15. Claim 5, drawn to a polysaccharide-protein conjugate comprising a polysaccharide of Group B streptococcus serotype Ia, classified in class 424, subclass 197.11
 16. Claim 5, drawn to a polysaccharide-protein conjugate comprising a polysaccharide of Group B streptococcus serotype Ib, classified in class 424, subclass 197.11
 17. Claims 5 and 15, drawn to a polysaccharide-protein conjugate comprising a polysaccharide of Group B streptococcus serotype II, classified in class 424, subclass 197.11
 18. Claims 5 and 15, drawn to a polysaccharide-protein conjugate comprising a polysaccharide of Group B streptococcus serotype III, classified in class 424, subclass 197.11
 19. Claim 5, drawn to a polysaccharide-protein conjugate comprising a polysaccharide

- of Group B streptococcus serotype V, classified in class 424, subclass 197.11
20. Claim 5, drawn to a polysaccharide-protein conjugate comprising a polysaccharide of Group B streptococcus serotype VIII, classified in class 424, subclass 197.11
 21. Claims 6 and 15, drawn to a polysaccharide-protein conjugate comprising an N-propionated meningococcal C polysaccharide, classified in class 424, subclass 250.1
 22. Claim 6, drawn to a polysaccharide-protein conjugate comprising an N-propionated meningococcal B polysaccharide, classified in class 424, subclass 250.1
 23. Claim 6, drawn to a polysaccharide-protein conjugate comprising an N-propionated meningococcal Y polysaccharide, classified in class 424, subclass 250.1
 24. Claim 6, drawn to a polysaccharide-protein conjugate comprising an N-propionated meningococcal W135 polysaccharide, classified in class 424, subclass 250.1
 25. Claim 42, drawn to a method of active immunization of a mammal against *Streptococcus pneumoniae* by administering an N-propionated polysaccharide-protein conjugate, classified in class 424, subclass 244.1
 26. Claim 43, drawn to a method of active immunization of a mammal against Group B *Streptococcus* by administering an N-propionated polysaccharide-protein conjugate, classified in class 424, subclass 244.1
 27. Claim 44, drawn to a method of active immunization of a mammal against Group B *Neisseria meningitidis* by administering an N-propionated polysaccharide-protein conjugate, classified in class 424, subclass 250.1
 28. Claim 45, drawn to a method of active immunization of a mammal against Group C *Neisseria meningitidis* by administering an N-propionated polysaccharide-protein conjugate, classified in class 424, subclass 250.1
 29. Claim 46, drawn to a method of active immunization of a mammal against *Haemophilus influenzae* type B by administering an N-propionated

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- polysaccharide-protein conjugate, classified in class 424, subclass 256.1
30. Claim 33, drawn to a method of making a beta-propionamido-linked polysaccharide-protein conjugate wherein the polysaccharide is derived from a yeast, classified in class 424, subclass 194.1
 31. Claim 33, drawn to a method of making a beta-propionamido-linked polysaccharide-protein conjugate wherein the polysaccharide is derived from cancer cells, classified in class 424, subclass 194.1
 32. Claim 33, drawn to a method of making a beta-propionamido-linked polysaccharide-protein conjugate wherein the polysaccharide is derived from chemical synthesis, classified in class 424, subclass 194.1
 33. Claim 34, drawn to a method of making a beta-propionamido-linked *E. coli* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
 34. Claim 34, drawn to a method of making a beta-propionamido-linked *Meningococcus* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
 35. Claim 34, drawn to a method of making a beta-propionamido-linked *Streptococcus* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
 36. Claim 34, drawn to a method of making a beta-propionamido-linked *Pneumococcus* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
 37. Claim 34, drawn to a method of making a beta-propionamido-linked *Haemophilus* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
 38. Claim 34, drawn to a method of making a beta-propionamido-linked *Neisseria* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
 39. Claim 34, drawn to a method of making a beta-propionamido-linked *Salmonella* polysaccharide-protein conjugate, classified in class 424, subclass

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40. Claim 34, drawn to a method of making a beta-propionamido-linked *Klebsiella* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
41. Claim 34, drawn to a method of making a beta-propionamido-linked *Pseudomonas* polysaccharide-protein conjugate, classified in class 424, subclass 194.1
42. Claim 52, drawn to an antibody immunoreactive with an N-acetylated yeast polysaccharide, classified in class 530, subclass 388.4
43. Claim 52, drawn to an antibody immunoreactive with an N-acetylated polysaccharide from cancer cells, classified in class 530, subclass 388.8
44. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *E. coli* polysaccharide, classified in class 424, subclass 169.1
45. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Meningococcus* polysaccharide, classified in class 424, subclass 150.1
46. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Pneumococcus* polysaccharide, classified in class 424, subclass 165.1
47. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Streptococcus* polysaccharide, classified in class 424, subclass 165.1
48. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Haemophilus* polysaccharide, classified in class 424, subclass 137.1
49. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Neisseria* polysaccharide, classified in class 424, subclass 164.1
50. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Salmonella* polysaccharide, classified in class 424, subclass 150.1
51. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Klebsiella* polysaccharide, classified in class 424, subclass 137.1
52. Claim 53, drawn to an antibody immunoreactive with an N-acetylated *Pseudomonas* polysaccharide, classified in class 424, subclass 170.1
53. Claims 55-58, drawn to a method of passive immunization by administering an

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antibody, classified in class 514, subclass 2.

Claims 3, 17 and 38, with respect to the bacterial polysaccharide, are considered linking claims and would be joined with one of inventions 1-6 and 10-24, if elected.

Claims 4 and 39, with regard to the *E. coli* polysaccharide, are considered linking claims and would be joined with one of inventions 1 and 2, if elected.

Claims 4 and 39, with regard to the *Pneumococcus* polysaccharide, are considered linking claims and would be joined with one of inventions 3 and 4, if elected.

Claims 4 and 39, with regard to the *Streptococcus* polysaccharide, are considered linking claims and would be joined with one of inventions 5, 6 and 15-20, if elected.

Claims 4 and 39, with regard to the *Meningococcus* polysaccharide, are considered linking claims and would be joined with one of inventions 21-24, if elected.

Claims 1, 2, 8-14, 16, 18, 21-28, 37 and 40 are considered linking claims and would be joined with one of inventions 1-24, if elected.

Claim 33, with regard to the method wherein the polysaccharide is derived from bacteria, is considered a linking claim and would be joined with one of inventions 33-41, if elected.

Claims 41 and 47 are considered linking claims and would be joined with one of inventions 25-29, if elected.

Claim 52, with regard to the antibody to a bacterial polysaccharide, is considered a linking claim and would be joined with one of inventions 44-52, if elected.

Claims 29-32, 35 and 36 are considered a linking claims and would be joined with one of inventions 30-41, if elected.

Claims 48-51 and 54 are considered linking claims and would be joined with one of inventions 42-52, if elected.

4) Inventions 1 through 53 are distinct from one another. Inventions 1 through 24 and inventions 42 through 52 respectively are drawn to two distinct products: polysaccharide-protein conjugates and antibodies, which differ in their structure, functions, sources, biological and immunological properties and belong to two different classes. Inventions 1 through 24 are drawn to polysaccharide-protein conjugates comprising distinct polysaccharides from different sources, wherein polysaccharides differ from one another structurally and/or immunogenically and

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biologically. Although some of the inventions belong to the same class/subclass, the polysaccharides used in these inventions are structurally distinct, requiring non-coextensive searches.

5) Inventions 25 through 29, inventions 30 through 41 and invention 53, respectively, are directed to distinct methods: method of active immunization, method of making a polysaccharide-protein conjugate and method of passive immunization. These methods differ from one another in method parameters, steps, reagents or compositions used and ultimate goals accomplished.

6) Inventions 1 and 2 and invention 33 are related as products and process of making the products. Similarly, inventions 3 and 4 and invention 36 as well as inventions 5 and 6 and invention 35 are related as products and process of making the products. Inventions 7 and 30, inventions 8 and 31, inventions 9 and 32, inventions 10 and 37, inventions 11 and 38, inventions 12 and 39, inventions 13 and 40, inventions 14 and 41, inventions 15-20 and invention 35 as well as inventions 21-24 and invention 34, respectively, are related as products and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the product of the cited inventions can be made by a materially different process, for example, by direct synthesis of the beta-propionamido-linked polysaccharide without involving steps A) and B).

7) Inventions 3 and 4 and invention 25 are related as products and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the process of immunizing a mammal against *Streptococcus pneumoniae* of invention 25 can be practiced by administering a materially different product other than pneumococcal type 4 or type 14 polysaccharide, such as, a PspA pneumococcal protein. Further, the polysaccharide-containing product of inventions 3 or 4 can be used in a materially different process, for example, in an *in vitro* diagnostic assay, as a source of

coating antigen.

8) Inventions 10 and 29 are related as product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the process of immunizing a mammal against *Haemophilus influenzae* type B of invention 29 can be practiced by administering a materially different product other than the *Haemophilus influenzae* type B polysaccharide, such as, an outer membrane protein vaccine. Further, the polysaccharide-containing product of invention 10 can be used in a materially different process, for example, in an *in vitro* diagnostic assay, as a source of coating antigen.

9) Invention 11 and inventions 27 and 28 are related as product and process of use of the product. Similarly, inventions 21 and 28, inventions 10 and 29, and inventions 22 and 27 are related as product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the process of immunizing a mammal against groups B and C *Neisseria meningitidis* of inventions 27 and 28 can be practiced by administering a materially different product other than the *Neisseria meningitidis* polysaccharide, such as, a meningococcal outer membrane protein vaccine. Further, the polysaccharide-containing products of inventions 11, 21 and 22 can be used in a materially different process, for example, in an *in vitro* diagnostic assay, as a source of coating antigen.

10) Inventions 15-20 and invention 26 are related as product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the process of immunizing a mammal against Group B *Streptococcus* of invention 26 can be practiced by administering a materially

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different product other than the polysaccharide, such as, a streptococcal protein antigen. Further, the polysaccharide-containing product of each of inventions 15-20 can be used in a materially different process, for example, in an *in vitro* diagnostic assay, as a source of coating antigen.

11) Inventions 42-52 and invention 53 are related as product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the antibody products of inventions 42-52 can be used in a materially different process, for example, in an *in vitro* diagnostic assay, as a diagnostic reagent, or in immunopurification of respective polysaccharides, or as an antigen source for production of anti-idiotypic antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, restriction for examination purposes as indicated is proper.

12) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's

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supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD

S. Devi, Ph.D.
Patent Examiner
March 2001